



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,062	03/30/2004	Joel S. Bader	21402-139CON (Cura-439CON)	7978
7590	09/15/2006		EXAMINER	
Ivor R. Elrifi Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C One Financial Center Boston, MA 02111			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,062

Applicant(s)

BADER ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☒ Claim(s) 11 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/30/04 (2 IDS's).
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Information Disclosure Statement

The information disclosure statements (IDS's) filed on 3/30/04 have been considered in full.

It is noted that the specification provides a list of references on pages 15-16. Applicant is reminded that a listing of references in the specification is not a proper information disclosure statement as set forth under 37 CFR 1.98(b). Therefore, unless the references have been cited by the examiner on form PTO-892 or on one of the IDS's filed 2/11/02 or 1/27/03, they have not been considered.

Specification

The amendment filed 3/30/04 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: incorporation by reference of 09/973,449. This application was not incorporated by reference into the original specification, and therefore is not part of the "original disclosure." Although the preliminary amendment incorporating 09/973,449 by reference was filed on the same day as the rest of the disclosure, the amendment is not referred to in the executed declaration, and therefore is not considered part of the "original disclosure." Applicant is reminded that the new rules pertaining to preliminary amendments applies to application

Art Unit: 1631

filed after September 21, 2004. The instant application was filed in March, 2004 and therefore is subject to the "old" rules.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claims 11 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 11 and 22 appear to recite an intended use for the methods of claims 1 and 13, respectively.

Neither recites an active, positive method step nor any limitation of a previously recited step nor a limitation of any other element of a parent claim. Applicant is reminded that an intended use is generally not accorded any patentable weight where it merely recites the purpose of a process. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The intended use recited in claims 11 and 22 does not materially limit the process steps of claims 1 and 13, respectively, and is therefore not considered a limitation of the methods of the parent claims. For these reasons, claims 11 and 22 fail to further limit the methods of their respective parent claims and are objected to.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to methods for detecting an association between a genetic locus and a phenotype comprising steps of mathematical/statistical manipulation. None of the claims recites a physical transformation of matter. Method claims which do not recite a physical transformation of matter MAY be statutory where they recite a concrete, tangible and useful result. In the instant claims, the last step is one of "determining" that an association exists IF an allele frequency difference is larger than a predetermined amount. It is noted that the claims do not actually recite determining whether an association does or does not, in fact exist, therefore the claims fail to recite a concrete result. No tangible expression of a result (e.g. output, display, etc.) is recited, therefore the claims also fail to recite a tangible result. As the claims do not recite either a physical transformation of matter or a concrete, tangible and useful result, they are not directed to statutory subject matter, and are rejected.

For a complete description of statutory subject matter with regard to computer-implemented-types of methods, applicant is invited to review the Interim Guidelines for Subject Matter Eligibility published in an OG Notice on 11/22/2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites use of an "Eq. 2" and claim 13 recites use of an Eq. 1", each in a step (b). None of the claim recites an actual equation. The specification sets forth equation labeled "Eq. 1", "Eq. 1" and "Eq. 3" on page 8. It is noted that the specification teaches a plethora of equations in addition to those of page 8. It is unclear what equations or equations applicant intends, if any, to be represented by the "Eq. 1" and Eq. 2" recited in the instant claims, therefore the claims are indefinite.

Applicant's attention is directed to MPEP 2173.05(s), which states, "Where possible, claims are to be complete in themselves. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted)."

If applicant intends "Eq. 1" and "Eq. 2" to represent the specific equations disclosed on page 8 of the specification, then the claims are further indefinite as it is unclear what the terms of the equations are intended to represent. For example, page 7 of the specification teaches that for a normal standard deviate z (standard deviate of what?), α is defined in terms of deviate z_{α} . However, page 7 also defines z_{α} as being equal to a constant (5.33) for a genome scan. Does applicant intend z_{α} to be a

Art Unit: 1631

constant or a variable in Eq. 1 of page 8? If a constant, what is it? If a variable, how is it to be determined for the specific method recited in the claims?

For the reasons set forth above, claims 1 and 13 are indefinite. As claims 2-12 and 14-23 fail to remedy the indefiniteness of parent claims 1 and 13, claims 2-12 and 14-23 are also indefinite. As the equations intended are unknown, the claims were deemed unsearchable (see below with regard to "relevant" prior art).

Claims 1, 5, and 6 recite the term "predetermined" as applied to an "upper limit" and a "lower limit" of phenotypic values. No step of "determining" a limit, either upper or lower, is recited in the claims, therefore it is unclear what is meant by a "predetermined" limit. The specification does not set forth limits for phenotypic values nor exemplify any particular "upper" or "lower" limits which may be taken as definitions of a "predetermined" upper or lower limit. As one skilled in the art would not know the metes and bounds intended by applicant for a "predetermined" upper or lower limit of phenotypic values, the claims are indefinite.

Claims 1 and 13 recite the term "predetermined value" with regard to an allele frequency difference. There is no step of "determining" a value of an allele frequency difference in the claims, therefore it is unclear what is meant by a "predetermined value". The specification does not set forth or exemplify any "values" which may be taken to be a definition of a "predetermined value". As one skilled in the art would not know the metes and bounds intended by applicant for a "predetermined value", the claims are indefinite.

Claim 5 limits the setting of a lower limit and an upper limit such that a pool (of DNA) "ranges" to include various percentages of a population. Once a limit is set, then the membership of the pool which results is generally also considered "set"; i.e. static. It is therefore unclear whether applicant intends the lower (and/or upper) limit to be variable such that the resulting pool membership falls within the stated range, or intends the pool membership itself to be variable despite having a set limit. As it is unclear what limitations applicant intends, the claim is indefinite.

Claims 8 and 19 recite the term "may be" with regard to individuals. The term "may be" renders the claims indefinite as it is unclear whether the phrase(s) following the term are intended to be positive limitations. This rejection may be overcome by replacing "may be" with --are-- in each claims, if this is consistent with applicant's intent.

Claims 11 and 22 recite a limitation of method claims "for determining the genetic basis of disease predisposition". It is unclear what limitation of each parent method is intended. No active method steps are recited in either claim, nor does either claim recite any limitation of a previously recited method step. See above. As it is unclear what, if any, limitation of a parent claim is intended, claims 11 and 22 are indefinite.

Conclusion

Claims 1-23 are rejected; claims 11 and 22 are objected to.

The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure is MURANTY et al. (Genet. Res. (1997) Vol. 70, pp. 259-265). MURANTY teaches a method of selective genotyping similar to that claimed wherein

Art Unit: 1631

formulae are used to determine the optimal number of individuals for use in selecting pools. MURANTY teaches that his formulae are obtained in the first two steps in a computer program (p. 263), but does not specifically teach what formulae or equations were used, therefore the examiner can not determine whether the formulae of MURANTY are the same as those interpreted to be recited in the instant claims (see above). Applicant invited to comment on any differences, if known, between the equations of the instant specification and those of MURANTY.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
9/12/06